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(54) A METHOD AND AN ARRANGEMENT FOR MANUFACTURING WOUND DRESSINGS, AND A WOUND DRESSING MANUFACTURED IN ACCORDANCE WITH THE METHOD

VERFAHREN SOWIE ANORDNUNG ZUM HERSTELLEN VON WUNDVERBÄNDEN SOWIE MIT DIESEM VERFAHREN HERGESTELLTER WUNDVERBAND

PROCEDE ET EQUIPEMENT POUR FABRIQUER DES PANSEMENTS, ET PANSEMENT FABRIQUE SELON CE PROCEDE

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Description

The present invention relates to a method and to an arrangement of apparatus for manufacturing wound dressings of the kind which comprise a perforated carrier material and a layer of hydrophobic silicone gel which lies against the wound, or sore, when the dressing is worn. The invention also relates to a wound dressing manufactured in accordance with the inventive method.

A wound dressing of this kind is known from our EP-A-0 261 167, in which the carrier material is fully enclosed by the silicone gel although while leaving openings through the dressing. When manufacturing a dressing of this kind, the carrier material is dipped into a mixture of those components which, when cured, form the hydrophobic silicone gel, and the carrier material is then transferred to a curing oven in which the carrier material is cured. In order to ensure that the silicone gel is uniformly distributed on both sides of the carrier material and that the perforations do not become clogged with gel, the carrier material is guided in the oven in a relatively complicated path. This known method is not suited to high production rates. Another wound dressing of the abovementioned kind is known from EP-A-251 810 which document discloses the features of the preamble of Claims 1, 4 and 6.

The object of the present invention is to provide a method which will enable such wound dressings to be manufactured at a high production rate and in a simple and reliable manner.

The invention also relates to apparatus for carrying out the method to a wound dressing suitable for manufacture by means of the inventive method.

To this end, a method of manufacturing wound dressings including the step of applying a coating of curable silicone mixture to the upper surface of a perforated carrier material and then applying heat to the silicone mixture until it has cured is characterized by blowing cold air onto the underside of the coated carrier material so that the silicone mixture is blown away from the perforations in the carrier material so as to form through penetrating perforations and prevent clogging of the perforations in the carrier material before the applying of heat. At the same time, the cold air flow ensures that the silicone mixture will not begin to cure before it has time to spread over the carrier material. The flow of air through the carrier material will, of course, also prevent the silicone mixture from running through the perforations in said material.

An arrangement for carrying out the aforedescribed method is characterized in that the arrangement includes an air-blowing unit which functions to blow cold air onto the underside of the carrier material so that the silicone mixture is blown away from the perforations in the carrier material so as to form through penetrating perforations and prevent clogging of the perforations in the carrier material and which is placed opposite the coating means.

A wound dressing suited for manufacture by means of the aforesaid method is characterized in that the carrier material is impervious to air and fluid, or only slightly permeable to air and fluid in the parts thereof lying between the perforations; and in that the carrier material has a silicone gel coating on solely one side thereof.

The invention will now be described in more detail with reference to an exemplifying embodiment thereof and also with reference to the accompanying drawings, in which

Figure 1 is a schematic perspective view of part of an inventive arrangement for manufacturing a wound dressing, and also illustrates an exemplifying embodiment of an inventive wound dressing manufactured by means of said arrangement;

Figure 2 is a cross-sectional view taken on the line II-II in Figure 1; and

Figure 3 is a cross-sectional view of another exemplifying embodiment of an inventive wound dressing.

Figure 1 illustrates schematically part of an arrangement for manufacturing an inventive wound or sore dressing. The arrangement includes a unit in the form of an extruder nozzle 1 for coating a perforated carrier material 2 with a thermosetting silicone mixture 3 which includes components which when cured form a chemically cross-linked, sticky silicone gel, for instance the silicone gel which is retailed by Dow Corning and specified in the aforesaid EP-A-0 261 167, or the silicone gel retailed by Wacker Chemie GmBH and designated Wacker RTV-2, VP7612. The carrier material 2 is moved in the direction shown by the arrow in Figure 1, by means not shown. These means may conveniently comprise a belt conveyor, a stentor means, to which the long side edges of the carrier material are attached, or some like means. Mounted beneath the movement path of the carrier material is an air-blowing unit 4, which extends from the nozzle 4 to a point located slightly downstream thereof. A further air-blowing unit 5 is also mounted beneath the movement path of the carrier material 2, downstream of the blower unit 4.

The arrangement operates in the following manner:

The perforated carrier material 2 is unrolled onto a conveyor, preferably from a storage reel, and is moved by the conveyor in under the extruder nozzle 1 by means of which the carrier material is coated with the thermosetting silicone mixture 3, which prior to curing has the consistency of a thick, viscous fluid. Cold air is blown onto the underside of the carrier material with the aid of the unit 4 and the air flows through the perforations 6 in the carrier material, as illustrated with arrows in Figure 2, and blows away the silicone mixture in the regions above the perforations, so as to provide through penetrating holes in the silicone mixture. The carrier material 2 coated with silicon mixture 3 is then moved to

a position above the blower unit 5, which blows hot air onto the underside of the carrier material. The silicone mixture will then begin to cure in the regions around the perforations, where the exchange of heat is greatest. When the regions around the perforations have cured sufficiently, the supply of hot air is preferably cut-off and the carrier material coated with said silicone mixture is passed into a curing oven.

Hot air shall not be blown onto the carrier material in the initial stage of the manufacturing process, since it is necessary for the silicone mixture to spread and be properly dispersed over the carrier material before the curing process begins. It is also important that the nozzle 4 is not heated, since this will incur the risk of the nozzle becoming blocked or clogged.

In order to prevent the silicone mixture from being blown from the carrier material, it is essential that the carrier material is impervious to air, or at least so impervious that essentially all air will flow through the perforations. However, material which permits air to diffuse therethrough can be used beneficially when practicing the invention. The carrier material shall also be impervious to fluid, or at least have a fluid-permeability which is so low that the thick-viscous fluid, i.e. the silicone mixture prior to curing, is unable to run therethrough.

Suitable carrier materials are relatively soft plastic sheets, such as polyethylene, polyamide, polyurethane, silicone film, etc.

The plastic sheet may also be microporous, i.e. have a sufficiently low fluid and air-permeability to satisfy the aforesaid requirements, so as to present a large surface area for adhesion between plastic sheet and silicone mixture. In order to ensure good adherence between silicone gel and plastic sheet, the plastic sheet may be coated with a silicone primer, for instance with Dow Corning 355 Medical Adhesive.

Another method of ensuring good adherence between silicone gel and carrier material is to use a perforated two-ply material as the carrier material. This two-ply material may, for instance, consist of a laminate which comprises a plastic sheet and a layer of nonwoven or textile material which can be laminated with the aid of heat or a binding agent. The two-layer material may also be comprised of a coated fibre material having a plastic film moulded on one side thereof.

That side of the carrier material which is not coated with silicone gel will preferably have a uniform and smooth surface, so as to have low adherence to any dried wound fluid which may have exuded through the perforations as the dressing is worn. This is particularly important when the dressing is used together with an overlying absorbent body or pad, since it must be possible to remove the absorbent body without the dressing being disturbed as a result of wound fluid that has dried on the absorbent body adhering to the carrier material and entraining the material in the initial stages of removing the absorbent body.

Figure 3 illustrates a further embodiment of an inventive wound dressing. This wound dressing differs from the dressing illustrated in Figures 1 and 2, insomuch that the carrier material 7 is comprised of a plastic film having perforations 8 provided in the bottoms of cup-shaped projections in the plastic film. Such plastic films are known to the art and are sometimes used as casing sheets for diapers and similar absorbent articles. In addition to the surface area for adhesion between silicone gel and the plastic sheet being greater than the surface area of the embodiment of the inventive dressing described with reference to Figures 1 and 2, the cupped shape of the projections 9 also reduces the risk of non-cured silicone mixture running down into the perforations 8 during the process of manufacture. This obviates the need, or at least greatly reduces the need, of blowing hot air onto the carrier material before passing the carrier material and its silicone coating into a curing oven.

When practicing the method of manufacture taught by EP-A-0 261 167, it is necessary to transport that part of the material to be embraced by silicone gel in an unsupported fashion. When practicing the present invention, on the other hand, the carrier material can be transported on an air-permeable conveyor, provided that the holes in the conveyor are sufficiently large to ensure that the delivery of air onto the underside of the carrier material will not be disturbed thereby. Thus, when practicing the inventive method, the carrier material can be transported at a higher speed than in the case of the aforesaid known method and the conveyor path can be guided much more easily than in the earlier known case.

In the case of the described embodiment of the inventive method of manufacture, the carrier material is comprised of a continuous web which is moved past the nozzles and the air-blowing units. Although this embodiment is to be preferred, it lies within the scope of the invention to hold the carrier material stationary and to move nozzles and air blowers in relation to said material.

As will be understood, modifications can be made to the described embodiment of the inventive arrangement for manufacturing an inventive wound dressing within the scope of the present invention. For instance, the air-blowing units 4 and 5 may be combined to form a single unit and may be supplied with air under pressure from one and the same source, for instance from the same blower fan, which may be beneficial in obtaining an homogenous air flow in the longitudinal direction. The hot air section of such a unit will include an appropriate heat source, such as electrical heating wires or filaments. Furthermore, at least the hot air-blowing unit will be conveniently accommodated in a housing which will enable the heat content of the hot air to be better utilized for delivering heat to the silicone mixture coated on the carrier material from above.

This invention thus provides a simple and effective method of manufacturing a wound dressing having a layer of hydrophobic silicone gel which is intended to lie against the wound or sore, and a layer of carrier mate-

rial which when the dressing is worn faces outwardly and which is not sticky and will not adhere to clothing and the like. As in the case of the aforesaid known dressing, the layer of hydrophobic silicone gel which lies against the wound or sore is soft and adheres to dry skin, and the inventive dressing will therewith facilitate healing of the wound in the same beneficial fashion as the known dressing. According to the present invention, the silicone gel is comprised of chemically cross-linked, two-component addition-curing silicone gel.

The carrier material will preferably have 0.5-200 perforations per cm^2 and the perforations will preferably have a diameter of 0.1-2 mm. When practicing the inventive method of manufacture, good homogeneity is obtained with regard to the size of the perforations in the gel layer, therewith enabling an inventive dressing to be constructed for smaller-sized perforations than the aforesaid known dressing, without the risk of the perforations being clogged or blocked by silicone gel in the manufacturing process.

The silicone gels used in accordance with the present invention are soft and will adhere to dry skin but not to the wound or sore. This extremely low or weak adhesion to wounds as compared with other so-called non-adhesive dressings is achieved because the silicone gel has an extremely low surface tension and a surface chemistry which forms other types of adhesion forces on the wound surface than other polymeric and metallic materials used in such dressings, wherewith the strength at which the silicone gel adheres to the wound surface is weaker than practically all of these polymers and metallic materials. The silicone gel is also form-stable, i.e. it retains its original form when handled normally. Thus, the silicone gel undergoes no plastic deformations when the dressing lies against the wound or when the dressing is removed or when protective covering strips are peeled from the gel surface, etc. The gel surface obtained when practicing the inventive method is also very smooth and even, which also contributes to the poor adhesion of the gel layer to the wound surface. The majority of other types of so-called non-adhering dressings have a larger available surface area than the inventive dressing, as seen both macroscopically and microscopically, which results in stronger adhesion to the wound and to the dried wound fluid.

The strength at which the silicone gels used with the inventive dressing adhere to dry skin is considerably lower than the adhesive strength of those adhesives used with conventional self-adhesive tapes used to secure wound dressings, or those adhesives used with conventional self-adhesive wound dressings. Thus, the skin will not be damaged or injured by the adhesive silicone gel when removing the inventive dressing. One method of measuring this adhesive strength is to stick 25 mm wide strips of an inventive dressing onto dry skin and to allow a weight attached to one end of the strip to draw the dressing gravitationally from the skin at an angle of 160° thereto. The weight which will draw, or peel, the dressing from the skin at a speed of 1 mm/s can be determined with the aid of this test. The adherency measured in accordance with this test shall lie within the range of 5-200 g, preferably within the range of 20-60 g, in order to provide satisfactory adhesion and dressing peelability.

The hardness of the silicone gel is measured by means of a method in which a round steel rod having a flat end and a diameter of 9.2 mm is pressed into the gel to a depth of 5 mm. The force required to achieve this depth of penetration is measured during the process. A silicone gel suitable for use in an inventive dressing will have a hardness which lies in the range of 0.5-10 N. An optimum hardness value is 2 N.

The penetrability of a silicone gel is measured with the aid of a method in which a conical test body is allowed to sink gravitationally into the silicone gel. The number of mm through which the test body has sunk over a time period of 5 seconds constitutes the penetration value. In this test, there is used a cone obtained from Sommer & Runge AG and designated Petrotest Sommer & Runge 18-036.1, which is filled with glass spheres to a weight of 62.5 g. A silicone gel suitable for use in an inventive dressing will have a penetrability which lies within the range of 5-20 mm. An optimum penetrability value is 9 mm.

The tensile strength of a silicone gel is determined with the aid of a method in which a gel test strip is fastened vertically between two clamps, of which one can be moved at a constant speed. The strip is stretched to a point at which it fractures and the maximum fracturing force is recorded. A silicone gel suitable for use with an inventive dressing will have a tensile strength within the range of 1-8 N/10 mm in the case of a 3 mm thick strip, and will preferably be 4 N/10 mm.

In addition to adhering to dry skin, the silicone gel will also adhere to other dry surfaces, and a good estimate of the adherence of the gel to dry skin can be obtained by measuring the force with which the gel adheres to a highly polished steel plate. The adherence of the silicone gel to a steel surface is determined by means of a method in which a test strip of silicone gel is applied to a steel plate and the strip then drawn or peeled from the plate with the withdrawn part of the strip being held at an angle of 90° thereto. The force required to withdraw or peel the strip from the plate is recorded. A silicone gel suitable for use with an inventive dressing will have an adhesive force within the range of 0.5-10 N/50 mm, preferably 2 N/50 mm, as measured in accordance with this method.

Claims

1. A method of manufacturing wound dressings including the step of applying a coating of curable silicone mixture (3) to the upper surface of a perforated carrier material (2) and then applying heat to the silicone mixture until it has cured, **characterized** by blowing cold air onto the underside of the coated carrier material so that the silicone mixture

is blown away from the perforations in the carrier material so as to form through penetrating perforations and prevent clogging of the perforations in the carrier material before the applying of heat.

2. A method according to claim 1, **characterized** by blowing hot air onto the underside of the coated carrier material (2) after blowing cold air thereonto until the silicone mixture (3) has cured.

3. A method according to claim 2, **characterized** by interrupting the delivery of hot air onto the underside of said coated carrier material before the silicone mixture (3) has completely cured; and terminating the curing process in an oven.

4. An arrangement for manufacturing a wound dressing which comprises a perforated carrier material (2) and a layer of hydrophobic silicone gel (3), which arrangement includes means (1) for coating the upper surface of the carrier material with a mixture of components which when cured by means (5) for delivering heat to the component mixture applied to the upper surface of the carrier material form a silicone gel, **characterized** in that the arrangement includes an air-blowing unit (4) which functions to blow cold air onto the underside of the carrier material so that the silicone mixture is blown away from the perforations in the carrier material so as to form through penetrating perforations and prevent clogging of the perforations in the carrier material and which is placed opposite the coating means (1).

5. An arrangement according to claim 4, **characterized** in that the hot-air delivery means has the form of a hot-air blowing unit (5).

6. A wound dressing comprising a perforated carrier material (2) and a layer of hydrophobic silicone gel (3) which lies against the wound surface when the dressing is worn, **characterized** in that the carrier material is impervious to air and fluid, or only slightly permeable to air and fluid in the parts thereof lying between the perforations; and in that the carrier material is coated with silicone gel on only one side thereof.

7. A wound dressing according to claim 6, **characterized** in that the carrier material (2) is comprised of a relatively soft plastic film.

8. A wound dressing according to claim 7, **characterized** in that the plastic film is microporous.

9. A wound dressing according to claim 6, 7 or 8, **characterized** in that the carrier material (2) is coated with a silicone primer.

10. A wound dressing according to any one of claims 7-9, **characterized** in that the carrier material is comprised of a two-ply material, including a plastic layer and a layer of fibre material.

Patentansprüche

1. Verfahren zum Herstellen von Wundverbänden, umfassend den Schritt des Aufbringens einer Beschichtung aus aushärtbarer Silikonmischung (3) auf die obere Fläche eines perforierten Trägermaterials (2) und dann das Einbringen von Wärme in die Silikonmischung bis sie ausgehärtet ist, **gekennzeichnet** durch Blasen von kalter Luft auf die untere Seite des beschichteten Trägermaterials, so daß die Silikonmischung von den Perforationen im Trägermaterial weggeblasen wird, um durchdringende Perforationen zu bilden und um ein Verstopfen der Perforationen im Trägermaterial vor dem Einbringen von Wärme zu verhindern.

2. Verfahren nach Anspruch 1, gekennzeichnet durch Blasen von heißer Luft auf die untere Seite des beschichteten Trägermaterials (2) bis die Silikonmischung (3) ausgehärtet ist, nach dem Blasen von kalter Luft hierauf.

3. Verfahren nach Anspruch 2, gekennzeichnet durch das Unterbrechen der Zufuhr von heißer Luft auf die untere Seite des beschichteten Trägermaterials, bevor die Silikonmischung (3) vollständig ausgehärtet ist; und das Beenden des Aushärtprozesses in einem Ofen.

4. Anordnung zum Herstellen eines Wundverbandes, mit einem perforierten Trägermaterial (2) und einer Lage von wasserabweisendem Silikongel (3), welche Anordnung eine Einrichtung (1) umfaßt, zum Beschichten der oberen Fläche des Trägermaterials mit einer Mischung von Komponenten, die ein Silikongel bildet, wenn sie durch eine Einrichtung (5) zum Zuführen von Wärme zu der auf die obere Fläche des Trägermaterials aufgebrachte Komponentenmischung ausgehärtet wird, dadurch **gekennzeichnet**, daß die Anordnung eine Luftblaseeinheit (4) umfaßt, die zum Blasen von kalter Luft auf die untere Seite des Trägermaterials dient, so daß die Silikonmischung von den Perforationen in dem Trägermaterial weggeblasen wird, so daß durchdringende Perforationen gebildet werden und Verstopfen der Perforationen in dem Trägermaterial verhindert wird und die gegenüber der Beschichtungseinrichtung (1) angeordnet ist.

5. Anordnung nach Anspruch 4, dadurch gekennzeichnet, daß die Einrichtung zum Zuführen von heißer Luft die Form einer Heißluftblaseeinheit (5) hat.

6. Wundverband, mit einem perforierten Trägermaterial (2) und einer Schicht von wasserabweisendem Silikongel (3), die an der Wundoberfläche anliegt, wenn der Verband getragen wird, dadurch **gekennzeichnet,** daß das Trägermaterial luft- und flüssigkeitsundurchlässig ist, oder in seinen zwischen den Perforationen liegenden Teilen nur geringfügig luft- und flüssigkeitsdurchlässig ist; und daß das Trägermaterial mit Silikongel an nur einer seiner Seiten beschichtet ist.

7. Wundverband nach Anspruch 6, dadurch gekennzeichnet, daß das Trägermaterial (2) einen relativ weichen Kunststoffilm umfaßt.

8. Wundverband nach Anspruch 7, dadurch gekennzeichnet, daß der Kunststoffilm mikroporös ist.

9. Wundverband nach Anspruch 6, 7 oder 8, dadurch gekennzeichnet, daß das Trägermaterial (2) mit einem Silikonprimer beschichtet ist.

10. Wundverband nach einem der Ansprüche 7 bis 9, dadurch gekennzeichnet, daß das Trägermaterial ein zweilagiges Material umfaßt, was eine Kunststofflage und eine Lage von Fasermaterial beinhaltet.

Revendications

1. Procédé de fabrication de pansements, comprenant l'étape d'application d'un revêtement en mélange durcissable de silicone (3) sur la surface supérieure d'un matériau de support perforé (2) puis l'étape d'application de chaleur au mélange de silicone jusqu'à ce qu'il ait durci, caractérisé par un soufflage d'air froid sur la face de dessous du matériau de support recouvert, de sorte que le mélange de silicone est éliminé des perforations du matériau de support afin de former des perforations traversantes et d'empêcher le bouchage des perforations dans le matériau de support avant l'application de chaleur.

2. Procédé selon la revendication 1, caractérisé par un soufflage d'air chaud sur la face de dessous du matériau de support recouvert (2), après le soufflage d'air froid sur cette face, jusqu'à ce que le mélange de silicone (3) ait durci.

3. Procédé selon la revendication 2, caractérisé par une interruption de l'envoi d'air chaud à la face de dessous dudit matériau de support recouvert avant que le mélange de silicone (3) ait totalement durci et par le fait de terminer l'opération de durcissement dans un four.

4. Installation de fabrication de pansements comprenant un matériau de support perforé (2) et une couche (3) de gel de silicone hydrophobe, laquelle installation comprend un moyen (1) servant à recouvrir la surface supérieure du matériau de support avec un mélange de composants qui, quand il est durci par un moyen (5) servant à envoyer de la chaleur au mélange de composants appliqué sur la surface supérieure du matériau de support, forme un gel de silicone, caractérisée en ce que l'installation contient une unité (4) de soufflage d'air qui sert à souffler de l'air froid sur la face de dessous du matériau de support de sorte que le mélange de silicone soit éliminé des perforations du matériau de support afin de former des perforations traversantes et d'empêcher le bouchage des perforations du matériau de support, et qui est placé à l'opposé du moyen de revêtement (1).

5. Installation selon la revendication 4, caractérisée en ce que le moyen d'envoi d'air chaud a la forme d'une unité (5) de soufflage d'air chaud.

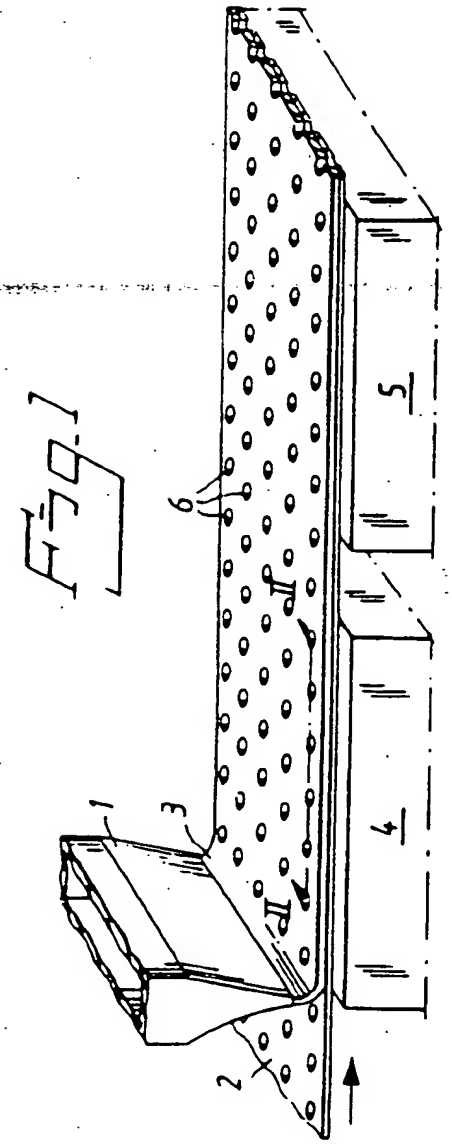
6. Pansement comprenant un matériau de support perforé (2) et une couche (3) de gel de silicone hydrophobe placée contre la surface de la plaie quand le pansement est utilisé, caractérisé en ce que le matériau de support est imperméable à l'air et aux fluides, ou n'est que légèrement perméable à l'air et aux fluides dans ses parties comprises entre les perforations, et en ce que le matériau de support n'est recouvert de gel de silicone que sur une de ses faces.

7. Pansement selon la revendication 6, caractérisé en ce que le matériau de support (2) est fait d'un film de matière plastique relativement mou.

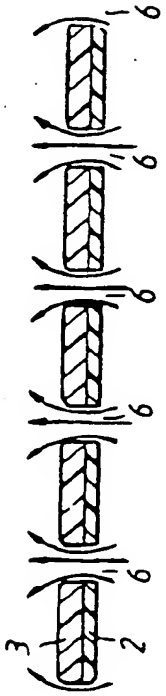
8. Pansement selon la revendication 7, caractérisé en ce que le film de matière plastique est microporeux.

9. Pansement selon la revendication 6, 7 ou 8, caractérisé en ce que le matériau de support (2) est recouvert d'une couche primaire d'accrochage du silicone.

10. Pansement selon l'une quelconque des revendications 7 à 9, caractérisé en ce que la matériau de support est composé d'un matériau à deux couches, comprenant une couche de matière plastique et une couche de matériau en fibres.



Фиг. 1



Фиг. 2

Фиг. 3